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MAR 08 2007

By this amendment, Applicants have amended claims 18 and 22 to more clearly define their invention. In particular, Applicants have deleted the phrase "hard-breathable" from claims 18 and 22 and instead clarified that the top sheet, with the outer sheet, keeps the urine absorbent material highly airtight. See, e.g., page 11, lines 10-14 of Applicants' substitute specification. Applicants have also recited that the urine receptacle includes a urine drainage port. See, e.g., element 4b in Figures 4(a) and 4(b), and the description at page 6, lines 3-5 of Applicants' substitute specification. Claims 18 and 22 have also amended to recite that the urine sensor detects urination in the vicinity of the urine drainage port. See, e.g., page 9, lines 18-20 of Applicants' substitute specification.

Claims 20, 21, 23 and 24 stand rejected under 35 U.S.C. 112, first paragraph. In support of this rejection, it is has been urged by the Examiner that the specification does not provide enablement for a specific composition of a top sheet which results in the claimed wet and dry breathable measurements. The Examiner alleges that a specific composition of the top sheet having the breathability measurements is required but not present in the disclosure as filed. Applicants traverse this rejection and request reconsideration thereof.

Applicants submit the Examiner has applied an improper standard in the enablement analysis. The standard for determining whether the specification meets the enablement requirement was casts in the Supreme Court decision of *Mineral Separation V. Hyde*, 242 US 261, 270 (1916), which indicated that the appropriate issue is whether the experimentation needed to practice the invention is undue or unreasonable. That standard is still the one to be applied. *In re Wands*, 858 F.2d 731, 737, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1988). Manual of Patent Examining

Procedure (MPEP) 2164.01. Accordingly, though the statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. *Wands*, *supra* 858, F.2d at 737, 8 USPQ 2d. 1404. The test for enablement is not whether any experimentation is necessary, but whether, if the experimentation is necessary, it is undue. *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976). The specification need not contain any example, as apparently alleged by the Examiner, if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. *In re Borkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970).

Here, Applicants have specifically described the hard breathability of the top sheet that can be used to achieve the characteristics presently claimed, i.e., together with the outer sheet keeping the urine absorbent material highly airtight and exhibiting the breathability measurements in claims 20, 21, 23 and 24. General examples of the materials that can be used for the top sheet are described in the paragraph bridging paragraphs 7 and 8 of the Applicants' substitute specification. In particular, it is disclosed that the top sheet can be made of, for example, polypropylene and polyolefin polyester blended with cotton. Applicants have provided examples and guidance as to how to measure the breathability. Finding specific materials which exhibit those characteristics can be achieved by those skilled in the art without undue experimentation. The Examiner has not demonstrated otherwise. Accordingly, claims 20, 21, 23 and 24 are supported by an enabling disclosure.

Claims 18 and 22 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over U.S. Patent No. 5,911,222 to Lawrence et al. in view of U.S. Patent No. 5,002,541 to Conkling et al. Applicants traverse this rejection and request reconsideration thereof.

The present invention relates to an automatic urine disposal device for discharging urine collected in an urine receptacle into a urine tank by using a vacuum pump, and to an urine receptacle used for an automatic urine disposal device to absorb urine discharge from a wearer's urinating part. According to the present invention, the urine receptacle comprises a substantially rectangular, non-breathable outer sheet, a urine absorbent material housed in the outer sheet, and an a liquid-permeable, non-woven fabric top sheet disposed on the surface of the urine absorbent material.

Moreover, according to the present invention as set forth in claims 18-24, the configuration includes that the urine absorbent material is accommodated in the outer sheet made of soft flexible materials, the top surface of the urine absorbent material is covered by the liquid-permeable, non-woven top sheet, the urine absorbent material is kept highly airtight by the top sheet and the outer sheet, the urine sensor is provided in the vicinity of the urine drainage port, the urine drainage tube made is of soft flexible materials, the urine is absorbed into the urine absorbent material through the holes on the top sheet upon the wearer's urination, and the urination is detected by the urine sensor and then the vacuum pump is activated. Due to this configuration, the urine receiver fits the wearer's body well, the wearer recognizes less wet feeling at the vicinity of urination, and thus he or she does not feel discomfort.

The inventors of the present invention focused attention to the following problems and solutions. That is, in order to prevent the wearer from feeling discomfort, it is difficult to reduce the wearer's wet feeling at the vicinity of urination only by effectively removing the urine from the surface as disclosed in the cited reference. Therefore, the inventors recognized that it is required to make the urine receptacle smaller and lighter in order to wear and keep the urine receptacle inside the wearer's underwear.

In contrast, the cited reference fails to disclose or suggest the following features set forth in the added claims 18-24: a top sheet that keeps the urine absorbent material highly airtight, use of soft flexible materials for the urine tube in order to provide the urine tube at the vicinity of wearer's urination without discomfort, urine drainage that is promptly absorbed into the urine absorbent material through the holes on the surface sheet upon urination with the urine drainage being detected promptly by the urine sensor arranged at the urine drainage port, and the discharged urine being transported to the urine tank by driving the vacuum pump.

The Lawrence et al. '222 patent discloses a liquid removal system having an interface device and a vacuum source. The interface device has a porous membrane with an entrance zone on one side. Specifically, the interface device is provided with a top or body contact surface 17 and a bottom or external surface 18. The side of the interface device opposite the body surface side 17 is a plastic shell 28. The interface device further comprises an entrance zone which may be filled with a fibrous foam or other type filling material 24. The interface device is provided with a coverstock material 21 over body contact surface 17. The coverstock material is preferably hydrophobic or treated so that it is rendered hydrophobic. A preferred material for the coverstock is a non-woven polymeric fibrous material such as

polypropylene which is hydrophobic yet capable of breathing. The coverstock is disclosed to be capable of repelling moisture by retaining the capacity to "breathe" so that there is a reduced risk of irritation to the skin. See, column 5, lines 31-44 of Lawrence '222.

Thus, while the cover stock material of Lawrence et al. '222 retains the capacity to "breathe," the top sheet used in the present invention, along with the outer sheet, keeps the urine absorbent material highly airtight. Since the top sheet together with the outer sheet keeps the urine absorbent material highly airtight, the urine can be easily drained by a vacuum pump. In fact, a vacuum even at low power can achieve higher urine collection using the top sheet of the present invention than a vacuum pump at a high power without such a top sheet. See, Figure 6 in the description at page 11, line 10 to page 12, line 14 of the substitute specification. A top sheet that (with the outer sheet) keeps the urine absorbent material highly airtight and the unexpectedly advantageous results achieved thereby are neither disclosed nor suggested by Lawrence et al. '222.

The Conkling et al. patent discloses a method and device for removing and collecting urine. The collecting vessel appears to be designed to be worn loosely to limit contact with the skin of the individual. See, e.g., column 5, lines 54-56 of Conkling et al. In any event, the collecting vessel appears to be of a quite different construction of the interface device of Lawrence et al. and the urine receptacle presently claimed. Accordingly, it is submitted there would have been no motivation to combine the teachings of Conkling et al. with those of Lawrence et al.

Moreover, the Examiner has apparently relied on the teachings of Conkling et al. only with respect to the use of a urine sensor. However, clearly nothing in Conkling et al. remedies any of the basic deficiencies noted above with respect to

Lawrence et al. Accordingly, claims 18 and 22 are patentable over the proposed combination of references.

Claims 19-21, 23 and 24 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lawrence et al. in view of Conkling et al. and further in view of International Publication No. WO 96/08223 to Reed et al. Applicants traverse this rejection and request reconsideration thereof.

The Reed et al. publication discloses a spyrosorbent wound dressing that exhibits differential moisture vapor transport rate properties. In particular, the sheet-formed composite dressing has a moisture vapor transport rate of greater than 2000 g/m²/24 hours when dry, and a wet to dry moisture vapor transport rate ratio in the range of about 1.5 to 10.

In the first place, the Reed et al. publication relates to a wound dressing, while the Lawrence et al. and Conkling et al. patents relate to urine removal systems. The Lawrence et al. patent discloses that the coverstock is capable of repelling moisture but retaining the capacity to "breathe" so that there is a reduced risk of irritation to the skin. The problems associated with a wound dressing which led the inventors in Reed et al. to make the wound dressing spyrosorbent are not disclosed to be same problems associated with the urine removal system. Accordingly, it is submitted there would have been no motivation to use the material of Reed et al. in the device with Lawrence et al. In any event, there is nothing to suggest that the wound dressing of Reed et al. would, with an outer sheet, keep a urine absorbent material highly airtight.

Finally, the Examiner admits that the Reed et al. patent does not have the dry breathability characteristics set forth in claims 20, 21, 23 and 24.

For the foregoing reasons, it is submitted there would have been no motivation to use the material of Reed et al. in the device of Lawrence. Moreover, it is submitted even the combined teachings of Lawrence et al., Conkling et al. and Reed et al. would not have suggested the subject material set forth in claims 19-21, 23 and 24.

For the foregoing reasons, favorable reconsideration and allowance of all of the claims now in the application are requested

To the extent necessary, applicants petition for an extension of time under 37 CFR 1.136. Please charge any shortage in the fees due in connection with the filing of this paper, including extension of time fees, to the deposit account of Antonelli, Terry, Stout & Kraus, LLP, Deposit Account No. 01-2135 (Case: 503.43626X00), and please credit any excess fees to such deposit account.

Respectfully submitted,

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